Transplant Centers: Re-Evaluation of Criteria for Medicare Approval (#CAG-00061N)

Summary of Town Hall Meeting on December 1, 1999

(Please Note: These summary notes were prepared by an outside contractor. They are intended to capture the major themes of presentations and statements. The Centers for Medicare & Medicaid Services does not ensure the accuracy of statements attributable to individuals in this summary.)

The Transplant Center Criteria Town Hall Meeting was held in the Auditorium of the Health Financing Administration (HCFA) in Baltimore, Maryland, on Wednesday, December 1, 1999. The current criteria used by HCFA to certify transplant centers to perform Medicare-covered whole organ transplants are more than 10 years old. Because of advances in transplant technology, HCFA wishes to revise these criteria.

The purpose of the meeting was to provide stakeholders in the transplant community, such as transplant recipients, transplant center administrators, surgeons and physicians, insurers, and the legal community, with the opportunity to provide input and suggestions on the type and content of the revised criteria. The goal of the meeting was not to reach a consensus on specific points or policies. Rather, the meeting's sponsor, HCFA's Coverage and Analysis Group, Office of Clinical Standards and Quality, sought to learn which aspects of the criteria need to be updated in light of current transplant technology and practice. Issues addressed included which aspects (medical, administrative, volume, outcomes, etc.) of transplant centers should be evaluated, the types of outcome measures that should be employed, the method of data submission required if periodic re-evaluation of centers is included in the new regulations, and the advantages and disadvantages of alternative thresholds for approving transplant centers (volume, outcomes, staff experience, etc.).

Robert Streimer, Deputy Director of the Office of Clinical Standards and Quality, opened the meeting by outlining U.S. Secretary of Health and Human Services Donna Shalala's position on transplants and what the Department hopes to achieve by revising the approval criteria for transplant centers. The Department desires to increase both the number and quality of transplants performed yearly and to save as many lives as possible. Thus, the new standards need to encourage performing sometimes difficult but lifesaving procedures, not just "easy" transplants known to have a high rate of success. In addition, the Secretary's office realizes that the current regulations spell out criteria for entry into the Medicare system, but do not provide guidance for re-certification or exit from the program. Mr. Streimer concluded by stressing the importance of this Town Hall Meeting as HCFA seeks input from the transplant community.

Following Mr. Streimer's presentation, Mr. Richard Coyne, Deputy Director, Coverage and Analysis Group, Office of Clinical Standards and Quality, HCFA, reminded the participants that the meeting was being both audiotaped and videotaped. He asked that anyone with questions please use the microphones in the center aisle to ensure that their comments were picked up by the recording equipment and clearly audible

to the audience.

The first panel addressed **Aspects of Facilities Linked to Coverage**. The panel consisted of Dr. William Payne, Dr. Lawrence Hunsicker, Dr. Amy Friedman, Dr. Michael Fisher who replaced his colleague Dr. Ronald Freudenberger, Dr. Ruud Krom, Dr. Glenn Barnhart, and Mr. John Crosby. Dr. Kenneth Simon served as the moderator.

Dr. William Payne, President of the United Network for Organ Sharing (UNOS) focused his comments on the need for HCFA's revised standards to be at least as stringent as the membership criteria use by UNOS and the Organ Procurement and Transplantation Network (OPTN). These criteria, especially the UNOS criteria, focus heavily on the experience and availability of transplant surgeons and physicians. Other aspects that should be covered by the criteria include standards for beds, equipment, laboratory support, blood banking, radiology, histology, mental health, social work, pediatrics, data submission, and referrals. He also emphasized the importance of membership in peer review groups and the use of quality measurement tools.

Dr. Lawrence Hunsicker from the University of Iowa Hospital and Clinic followed with a presentation focused on the use of volume as a criteria for Medicare certification. Currently, Medicare regulations require a minimum number of transplants per year for each organ type for certification. He noted that while volume per year does not seem to have an effect on the success of kidney transplants, heart and liver transplant centers with higher volumes tend to have better outcomes. Similarly, the per year volume seems to correlate more closely with outcomes than the cumulative volume at a particular center. He concluded by stating that the benefits to HCFA of using volume as a certification criteria include generally better survival rates at higher volume centers, even though some small volume centers do as well as their larger counterparts. Since these small centers may serve smaller or special populations, such a residents of Hawaii or pediatric patients, this should be taken into account when revising certification policy.

The small transplant center perspective was presented by Dr. Amy Friedman who represented the Yale University School of Medicine. She stressed small centers' emphasis on patient care, issues raised by the quality of donated organs, and the health of patients at the time of transplant, as well as the support small centers provide to large centers in the form of post-transplant patient care. Other issues raised by Dr. Friedman included: taking into account the quality of donated organs and the health of recipients when interpreting survival statistics; the fear that restrictive regulations will slow or eliminate innovation in transplant procedures and technology; and the difficulty of achieving good long-term results when Medicare only covers 80 percent of a patient's post-transplant medication for a three-year period.

Dr. Michael Fisher, Professor of Medicine at the University of Maryland, focused on revamping the heart transplant criteria. He believes that the current criteria encourage a large volume of transplant in "good" candidates (resulting in some transplants being performed too early) and does not emphasize appropriate use of medication to control conditions to avoid or delay transplantation. Dr. Fisher

suggested that Medicare evaluate transplant centers on the appropriate use of medication, functional capacity of candidates, survival rate of patients deemed too well to transplant, periodic reassessment of listed patients, and recordkeeping for de-listed patients.

Dr. Ruud Krom, who is affiliated with the Mayo Clinic, spoke from a reviewer's perspective. He indicated that the current guidelines make it difficult for reviewers to assess transplant programs. Since 1987, the overall one-year survival rate has increased, the number of newly certified centers has declined, and the number of centers reporting low survival rates has decreased from 43 percent to 16 percent. Because of these changes, Dr. Krom suggested adjusting the standards for certification to more accurately reflect survival rates in 1999. He also suggested that transplant center volume and experience may influence outcomes.

The final physician on this panel, Dr. Glenn Barnhart of the Sentara Norfolk Hospital Cardiac Transplant Program, addressed the difficulty of accurately assessing irreversible organ failure and the importance of evaluating the current credentials of centers' medical and surgical staff. He began comparing the ideal situation where recipient selection is based on the greatest likelihood of achieving good results over the long term with the reality of less than ideal candidates receiving organs because their physicians tend to give them "the benefit of doubt." The presence of multiple adverse factors, including behavior patterns such as smoking and other medical conditions such as diabetes, makes determining the cut-off point for transplantation in individual patients especially difficult. Suggestions presented by Dr. Barnhart included using the UNOS criteria for physician and surgeon credentials as a minimum requirement, requiring ongoing medical education and post-transplant patient contact, establishing local credentialing and re-credentialing guidelines, and examining the relationship between volume and outcomes.

The final panelist in this portion of the meeting was Mr. John Crosby, a heart transplant recipient. Mr. Crosby stressed the importance of good insurance coverage to its positive effect on a transplant candidate/recipient's peace of mind, as well as the importance of developing a relationship with the transplant center team. He emphasized that transplant recipients worry about what their insurance will cover and if it will limit their access to care, about reaching the limits of their benefits, and how to pay for medications for their follow-up care.

Audience comments following the panel presentation addressed the effectiveness of transplant centers' efforts to increase organ donation, the influence of the severity of a patient's illness on the outcome, the need for more rehabilitation and support services, societal priorities (quality of life versus survival), institutional issues such as changing ownership of facilities, the bonds between patients and their transplant team, and premature listing of candidates in hopes that early listing will improve their chance of receiving an organ.

The second panel, **Methodologies for Measuring Outcomes**, was moderated by Dr. Steven Clauser. Dr. Leah Bennett, Dr. Roger Evans, Dr. Dinesh Ranjan, Dr. Michael Dreis, Dr. Alan Langnas, and Ms. Flora Solarz served as panelists. Currently, Medicare uses actuarial survival data to evaluate transplant center outcomes. Since the number of centers performing transplants and the data available on individual

transplant candidates, recipients, and organ donors has increased in both quantity and quality since Medicare began covering transplants, HCFA asked these panelists to address the pros and cons of alternative outcome measurement tools. It is hoped that revised means of measuring outcomes will encourage the transplantation of individuals who are severely ill, but have reasonable expectations of a good outcome.

UNOS representative Dr. Leah Bennett provided an overview of the use of statistical methods for measuring outcomes. She noted that the Kaplan Meier techniques currently used by HCFA cannot handle multi-variable analyses of the type required to adjust for various levels of risk among transplant candidates/recipients. Absolute, relative, comparative, and efficiency measures were among those addressed in her presentation. Dr. Bennett suggested that HCFA examine the types of measurement methods available, determine which questions the Agency wants answered by the data analysis, and examine the assumptions associated with the various questions and methods before determining how to analyze transplant outcome data.

Support for unadjusted outcome measures was voiced by Dr. Roger Evans of the Mayo Clinic. He began by discussing the difference between prospective risk assessment (assigning risk based on existing characteristics) and retrospective risk adjustment (the use of risk measures to adjust quality assessments). Dr. Evans then asked if we, as a society, should reward inappropriate and costly patient selection instead of mandatory patient selection guidelines and increased physician accountability. In conclusion, Dr. Evans suggested abandoning risk adjustment and adopting penalties for poor decision-making concerning who receives the very scarce resource of available organs.

Dr. Dinesh Ranjan from the University of Kentucky opened his comments by asking whether the current threshold of 12 transplants per year for two years is sufficient for a good analysis of outcomes. Based on his experience, the critical number of transplants per year is approximately 20 procedures. Below this number, a single poor outcome has a significant impact on a center's statistics. Dr. Ranjan is affiliated with the transplant center at the University of Kentucky and noted that many of his patients are smokers. This led him to suggest that HCFA should take into account regional variations, other medical conditions, and referral patterns when developing outcome measures to replace the current ones. Other aspects besides survival that might be included in the evaluation of centers include quality of life, number and severity of complications, length of stay, and financial issues. Dr. Ranjan also supported periodic review and re-certification of transplant centers, as well as new indicators for accepting patients with hepatitis B and some cancers.

The Health Resources and Services Administration's (HRSA's) Office of Special Programs, Division of Transplantation was represented by Dr. Michael Dreis. Since the Agency's objective is to assure that transplant candidates and recipients experience good care and quality of life, the ultimate goal of revising the regulations should be to decrease morbidity while increasing the quality of patient care throughout the system. He indicated that risk adjustment levels the playing field by taking into account multiple factors. Since most measures look at post-transplant patient experience, Dr. Dreis suggested looking at pre-transplant issues such as patient selection, severity of disease, and medical treatment. He also emphasized

the need for better reporting and more timely submission of data.

Dr. Alan Langnas from the Nebraska Medical Center spoke from the health technology assessment point of view and directed his comments toward the issue of risk assessment in liver transplantation. The lack of a national database and the need for more support for research were among the issues touched on during this presentation. Of particular importance to Dr. Langnas was the idea of comparing similar patient groups. He noted that 40 year-old transplant recipients will have different survival rates that 65 year-old recipients simply because the second group will have more age-related deaths. Similarly, patients who received a liver for quality of life issues will have different outcomes than those who received one as a life saving measure. Dr. Langnas also indicated that policy makers should have access to the scientific data and that HCFA should provide guidelines on transplantation and not ask physicians to create policy on who should or should not receive transplants.

The final panelist was lung transplant recipient Flora Solarz. Ms. Solarz stressed that survival rates alone are not sufficient outcome measures and that minimum volume requirements at transplant centers are important. Pre-transplant mortality related to the unavailability of transplant surgeons is unacceptable and candidates should be turned down only on the basis of incompatibility. Of particular concern to Ms. Solarz were obstacles to patient compliance with post-transplant treatment regimes. Patient education, medicine side effects, lack of patient correlation between medication and survival, changes in medical benefits and the need for financial counseling, the difficulties of returning to a normal lifestyle after lengthy hospitalization, living with an invisible disability, and return to work issues are some of the factors affecting patient outcomes that need to be addressed in the revised regulations.

The question and answer period following the panel presentations focused on who should set standards and develop guidelines to identify the individuals to receive transplants. One position expressed was that the responsibility rested with the transplant community, while another held that the current regulations effectively make the decision by limiting Medicare payment to authorized centers meeting survival criteria. Other comments focused on the role of risk adjustment, insurance companies and other organizations paying for transplants besides Medicare and their role in limiting access to these procedures, the correlation between patient education and compliance, the stratification of the donor pool, and the significance of transplant team experience in the success of small centers.

The afternoon session began with a panel on **Data Used for Approving Centers**. Currently, Medicare requires hard copy submission of data as part of the certification process for transplant centers. Since the data submitted as part of the application process covers a relatively small number of cases, HCFA has been able to handle hard copy submission of this data. Should HCFA move toward periodic re-certification of transplant centers, the amount of data submitted will increase significantly. As a result, new systems for obtaining data electronically, ensuring data accuracy, and sharing information with centers and the public will need to be developed. Dr. Mary Ellison who substituted for Berkeley Keck, Dr. Paul Eggers, Ms. Carol Edwards, Ms. Mary Ann Palumbi, and Ms. Alexis Southworth addressed some of the options available to HCFA. Dr. David Naftel was unable to attend and did not send a

representative in his place. Ms. Marcia Newton served as moderator for this panel.

Dr. Mary Ellison, UNOS Director of Research, began the panel presentations by describing the UNOS database and its methods of data collection. The database allows for electronic submission, review, and modification through a secure, encrypted Internet site. It collects longitudinal data on transplant candidates/recipients from wait list through graft loss or death and currently contains more than two million records on approximately 200,000 individuals. Data submission is voluntary. UNOS uses a reminder system to prompt centers to submit or update data and reports a 68 percent compliance rate six months after transplant and a 90 percent compliance rate one year after transplant. The data collection forms were developed by UNOS with input from HCFA, HRSA, End Stage Renal Disease (ESRD) Networks, Office of Management and Budget, Food and Drug Administration, and the National Institutes of Health. Quality assurance processes include electronic audits, computer programs, audits of data entry staff, on-site auditing, and maintenance by individuals. UNOS members, transplant candidates/recipients, HCFA, HRSA, ESRD networks, professional organizations, the media, and the healthcare industry utilize this database.

The question of what the collected data should measure was the subject of the Director of HCFA's Division of Beneficiary Research, Office of Strategic Planning, Dr. Paul Eggers' presentation. He emphasized that just because something can be measured does not mean that it should be and that much thought needs to be given regarding the use of data in the best possible way. He also pointed out that no matter where the bar is set, whether based on outcomes or other aspects of facilities, a full 50 percent of the centers will fall below the median. Factors outside of the transplant centers' control, such as the amount of time a patient waits before coming under a center's care, should also be considered when developing regulations for the type of data submitted and the analyses performed.

Ms. Carol Edwards, representing St. Luke's Hospital in Houston, focused on the importance of not increasing the burden of data collection and submission on transplant centers. If HCFA increases data collection requirements, centers may experience financial or staffing difficulties. She also indicated that the acuity of illness must be taken into account when analyzing data and that centers should not be punished for using innovative approaches.

Representing the National Association of Transplant Coordinators, Ms. Mary Ann Palumbi commented on the type of data that should be considered for collection under a new system. She began by advocating the use of the current system and determining ways to better interpret and use the information currently available. If, however, a new system were to be adopted as a result of changes to the certification criteria, several issues need to be considered. The new system must be secure and encrypted. It should not require the purchase of new hardware. Most importantly, the system should be simple to use and require limited data entry. Ms. Palumbi suggested that any new system keep files on demographics for each center and allow comparison of the volume of patients evaluated versus those put on the waiting list. The volume of deaths while waiting, the number transplanted, and rates of graft survival or loss should also be available. She also advocated using a risk-adjusted model that would allow for adjustments based on specific circumstances

(such as managed care regulations) and a re-certification period of three to four years.

Ms. Alexis Southworth concluded the panel discussion by sharing her experiences as a renal disease patient and recipient of two separate kidney transplants. She acknowledged the benefits of data collection, but reminded the audience that poor data input, either in the content or correctness of data, yields bad information output and stressed the importance of timely submission of information. Access to quality care and patient education were factors that Ms. Southworth saw as key to patients/recipients getting better and living with their transplants.

In the discussion period following the panel, issues raised included the costs associated with collecting and analyzing data, the use of outlyer data to detect best practices, and the need for independent auditing of risk-adjusted data to prevent overcharacterization of risk. Also discussed were concerns about comparing the outcomes at new centers with sicker patients against those of established centers with healthier patients, the possible bias inherent in the data submitted by individual centers, and the possible loss of Medicare funding if a center falls below a strict numerical standard.

Thresholds for Approving Centers was the subject of the fourth and final panel. Currently, centers must exceed thresholds concerning medical standards, outcome and volume standards, and administrative conditions to be approved by Medicare. Under certain circumstances, centers can apply for a waiver of an individual threshold if it meets HCFA's overarching goal of ensuring quality transplant services. Dr. James Burdick, Dr. Mark Joensen, Dr. Henry Krakauer, Dr. Charles Moore, Dr. John McVicar, and Ms. Myra Fine presented the advantages and disadvantages of alternatives for establishing new thresholds or modifying existing ones. Ms. Rachael Weinstein served as the moderator.

A private practice surgeon's perspective was presented by Dr. James Burdick, Previous President, UNOS. Like several previous speakers, he began by stating that HCFA needs to have a clear understanding about what it wants to achieve in the revised regulations, especially in the areas of quality of care, number and location of centers, and access to centers before determining what changes, if any, will be made. As with all communities, any actions that affect one member or aspect of the community will have effects on other members or aspects. Dr. Burdick suggested that HCFA consider the personnel (especially physicians and surgeons), processes and institutional resources, and products (volume and outcomes) as thresholds to be included in the revised regulations. In addition, he cautioned that outcome data should be risk-adjusted, that a low volume of procedures could result in poor statistics, and that advances in the field cannot always be anticipated. Dr. Burdick concluded that HCFA might want to consider making the new regulations stricter than those currently employed by UNOS and OPTN.

Dr. Mark Joensen, Vice President, CONSAD Research Corporation, focused on possible goals for new criteria and enforcement policies and mechanisms. The protection of patient health, effective use of limited numbers of organs, motivation to improve morbidity and mortality outcomes, cost-effectiveness, creation of a framework for providing patients with up-to-date information, and minimization of

disincentives to register specific groups of patients were some of the goals suggested by Dr. Joensen. In addition, the new regulations should provide for enforcement of standards and a process for removal from the Medicare program if a center does not meet the threshold criteria. Items to be considered for the enforcement program include: availability of performance data; private notification to centers of failure to meet standards; public notification of a center's failure to meet standards; required development of an action plan to improve programs and correct deficiencies; staggered reimbursement levels based on performance; limitations of the number of Medicare patients listed through a particular center; and suspension or cancellation of Medicare certification. Dr. Joensen concluded by suggesting that threshold levels be adjusted based on the median performance of all centers, that multi-year outcomes be considered to offset low yearly volume at small centers, and that HCFA reward improvement in individual centers' performance.

The Office of the Assistant Secretary for Planning and Evaluation was represented by Dr. Henry Krakauer. The main focus of his presentation focused on ensuring that certification procedures fit in with the Agency's goals and obligations. Although he touched on the need to assess the whole transplant program (in terms of meeting needs, technological advances, and policy development), he focused on what should be assessed and how the assessment should be made for individual centers. Some of the issues related to assessing individual centers' performance include: whether to assess performance against an absolute or relative standard; what stages of a patient/recipient's care should be evaluated (at time of listing, during care at the center, during care at the center and follow-up, or some combination of these stages); and how to use the available data to assure the quality of the transplant program. Dr. Krakauer concluded his remarks by discussing the pros and cons of several methods of assessing performance, with an emphasis on risk-adjusted methods.

Dr. Charles Moore of the Christus Transplant Institute prefaced his remarks by noting that new and small centers face a "catch 22" situation in attempting to meet the minimum volume of transplants required for Medicare certification. Since programs working toward certification cannot draw from the pool of Medicare patients, they must build their statistics on a much smaller pool of patients covered by independent insurers. He proceeded to advocate the adoption of UNOS guidelines for certification and to address problems with retaining center certification in light of changes in staffing. As an example, Dr. Moore told of a center that was taken over by new ownership and retained its certification although virtually every member of its transplant team left for another center. Under current regulations, the departing team could not take their certification with them while the replacement team, which was less experienced, retained the center's certification. As a solution to such situations, Dr. Moore suggested that HCFA consider certifying transplant consortiums. He also emphasized HCFA's role as a watchdog and suggested it be allowed to sanction non-performing centers.

The University of California, Davis Medical Center was represented by Dr. John McVicar who discussed ways that small centers could overcome volume thresholds by citing the experience of a low volume heart transplant center. This center was able to attain Medicare certification although its volume was lower than the minimum usually required due to its perfect success rate. Dr. McVicar expressed concern that

small centers might have difficulty meeting minimum volume requirements, even though they provide quality care and have high rates of success. He also indicated that the thresholds currently specified for heart, lung, and liver transplants are not internally consistent.

The final presenter was Myra Fine, a heart transplant recipient. She stressed the importance of the attitude of a center's personnel and of the relationship between the staff and the patient/recipient. She also pointed out that Medicare regulations need to be easy to understand, while allowing for patient access. As an example, Ms. Fine cited current regulations that allow kidney patients to enter the Medicare transplant program immediately, while heart patients must wait two years. In addition to reforming waiting periods, Ms. Fine suggested the HCFA certify start-up facilities on a temporary basis for two years to provide Medicare patients greater access to services.

Questions following the panel discussion focused on the ideal number of centers and re-certification issues. One participant suggested that ESRD networks could serve as reviewers/auditors for re-certification. Another question sparked a discussion on whether HCFA should limit the number of centers or whether market forces should be allowed to determine the number of centers. The role of quality improvement efforts in the re-certification process, ways to address performance standards for small centers, and the importance of a transplant team's credentials were also addressed.

The general question and answer period following the final panel focused on the next steps for the review and revision of transplant center criteria. This session was moderated by Mr. Richard Coyne. Audience questions focused on: who would develop the proposed rules; whether experts in the field who are not affiliated with the government would be consulted; and when the proposed regulations would be available for review and comment. HCFA staff members working on the revisions indicated that they would consider the issues raised during the Town Hall Meeting, but that they were prohibited by Federal regulations from forming a panel of outside experts. Also, they indicated that there are no firm timelines for publishing the proposed regulations. Once the regulations have been revised, they will be published in the Federal Register with instructions for providing comments.

Dr. Hugh Hill concluded the meeting by thanking participants for their participation. He stressed the importance of the meeting and the opinions and feedback provided by presenters and audience members.